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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,654	08/19/2005	Clay B Marsh	18525/04133	7420

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CALFEE HALTER & GRISWOLD, LLP
800 SUPERIOR AVENUE
SUITE 1400
CLEVELAND, OH 44114

EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/519,654	Applicant(s) MARSH, CLAY B	
	Examiner Tamthom N. Truong	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 28-35 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 28-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Applicant's amendment of 9-5-06 has been fully considered. However, applicant's argument has not overcome the previous 102 rejection based on **Zimmermann et. al.** (WO'854). Thus, said rejection is maintained.

Claims 13-27 have been cancelled.

Claims 1-12 and 28-35 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 and 28-35 are rejected under 35 U.S.C. 102(b) as being anticipated by **Zimmermann et. al.** (WO'854).

As stated in the previous office action, Zimmermann et. al. disclose the free base of the compound 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl)pyrimidin-2-ylamino]phenyl]-benzamide (see page 1, line 13) which is the same as the claimed Compound I. Zimmermann et. al. disclose formula II, which is the *monomethanesulfonate salt* of that compound (see page 4), and is the same as the salt recited in claim 3, which falls within the scope of claim 2. The disclosed compound and its salt are used to treat cancers as well as

combating the haemotoxic effect of asthma, and treating diseases which respond to an inhibition of the PDGF receptor kinase (see page 11, lines 1-8 (first paragraph)). Page 12 further relates the activity of the disclosed compound and its salt to the *synergistic effects with other immunomodulatory or anti-inflammatory substances*. Thus, by inference, the reference teaches anti-inflammatory effect to the disclosed compound and its salt. Furthermore, the term “comprising” in the instant claims does not limit to Compound I and/or its monomethanesulfonate salt.

Applicant emphasizes that Zimmermann et. al. indicates that “[T]he methanesulfonic acid addition salt of a compound of formula I has **no significant effect on epithelial necrosis or infiltration by inflammatory cells**”. This means that said salt does not affect cell death of the epithelial layer, nor does it allow the response of inflammatory cells. It does not mean that the methanesulfonic acid addition salt has no anti-inflammatory effect. The sentence of “it does **markedly reduce fibroproliferation and occlusion of the lumen** compared with controls” indicates that methanesulfonic acid addition salt actually has anti-inflammatory effect which is why it has **synergistic effects** with other anti-inflammatory substances.

Applicant’s attention is directed to the reference of **Liebler et. al.** (Thorax, 1998, Vol. 53, pp. 823-829) which reveals that **fibroproliferation** is present early in the course of ARDS (Acute Respiratory Distress Syndrome – see the last paragraph on page 829), which is an inflammatory disease. Thus clearly, fibroproliferation is related to inflammation.

Applicant’s attention is also directed to the reference of **Lukacs et. al.** (Chest, 7/2001, Vol. 120 (1), Supplement 5S-8S), which shows that **fibroproliferation** is a part of chronic lung

disease which is initiated by inflammatory response (see the abstract on page 5S). Again, the relationship of fibroproliferation with inflammation has been established. Therefore, it is understood that any compound reducing fibroproliferation would reduce inflammation.

The references of **Liebler et. al.** and **Lukacs et. al.** are cited to show scientific principle only. They are not construed as secondary references.

The instant claims 4-6 and 28-33 which recite the limitations of *monocytes, M-CSF-stimulated monocytes, autoimmune diseases, arthritis, and lung injuries*. As disclosed in the "Background" of the invention, monocytes and M-CSF-stimulated monocytes are known to be involved in many inflammatory diseases. Therefore, it is understood that the *synergistic anti-inflammatory effect* of the disclosed compound and its salt would treat diseases where monocytes are involved such as: asthma, psoriasis, etc.

The instant claims 11, 12, 34 and 35 recite dosages which are disclosed on page 17, lines 14-16.

Thus, the reference's disclosure inherently teach the method recited in claims 1-12 and 28-35.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11-14-06


Tamthom N. Truong
Examiner
Art Unit 1624


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600